4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-1279]

Medical Device Development Tools; Draft Guidance for Industry, Tool Developers, and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Medical Device Development Tools." This document provides guidance to FDA staff, industry, healthcare providers, researchers, and patient and consumer groups on a new voluntary process within the Center for Devices and Radiological Health (CDRH) for qualification of medical device development tools (MDDT) for use in device development and evaluation programs. This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled "Medical Device Development Tools" to the Division of Small Manufacturers, International and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993-

0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-847-8149. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance.

Submit electronic comments on the draft guidance to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Kathryn O'Callaghan, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 3614, Silver Spring, MD 20993-0002, 301-796-6349.

SUPPLEMENTARY INFORMATION:

I. Background

The draft guidance describes the framework and process for the voluntary CDRH qualification of MDDT, including definitions of applicable terms, criteria for evaluating an MDDT for a specific context of use, the threshold for qualification, and the contents of a qualification submission. The intent of this voluntary qualification policy is to: (1) Enable faster, more efficient development of important life-saving and health-promoting medical devices; (2) promote the development of tools to facilitate more timely device evaluation; (3) provide a mechanism to better leverage advances in regulatory science; and (4) more quickly and more clearly communicate with CDRH stakeholders about important advances in regulatory science that may be leveraged to speed device development and regulatory evaluation. CDRH expects the qualification process to expedite development of publicly available tools which could potentially be used widely in multiple device development programs. Once an MDDT is

qualified for a specific context of use, it can be used by any medical device developer for that context of use.

At some point in the future, FDA may initiate a pilot program for MDDT qualification submissions, which would help inform final guidance on this topic. FDA would publicly announce such a program prior to initiation.

This guidance does not discuss the review of MDDTs submitted as part of a specific medical device regulatory submission, nor does it address the specific evidentiary standards or performance requirements needed for purposes of qualification of a specific MDDT.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on the qualification of MDDTs. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm. Guidance documents are also available at http://www.regulations.gov. To receive "Medical Device Development Tools," you may either send an email request to dsmica@fda.hhs.gov to receive an electronic copy of the document or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number 1882 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance contains information collection that is subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 812 have been approved under OMB control number 0910-0078; the collections of information in 21 CFR part 814 have been approved under OMB control number 0910-0231; the collections of information in 21 CFR part 807 subpart E have been approved under OMB control number 0910-0120; and the collections of information in 21 CFR part 809 have been approved under OMB control number 0910-0485.

V. Comments

Interested persons may submit either electronic comments regarding this document to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

Dated: November 4, 2013.

Leslie Kux,
Assistant Commissioner for Policy.

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